K000565

JUN 2 7 2000

510(K) Summary
for
NeuroMetrix NC-stat

1. SPONSOR

NeuroMetrix, Inc.
One Memorial Drive
Cambridge, MA 02142

Contact Person: Shai N. Gozani, M.D., Ph.D.
Chief Executive Officer
Telephone: 617-225-7774

Date Prepared: February 18, 2000

2. DEVICE NAME

Proprietary Name:	NC-stat
Common/Usual Name:	Nerve Conduction Monitoring System
Classification Name:	Nerve Conduction Velocity Measurement Device

3. PREDICATE DEVICE

The NeuroMetrix NC-stat is a modification of, and is substantially equivalent to, the NC-stat described in K982359.

4. DEVICE DESCRIPTION

The purpose of this submission is to obtain clearance to market a modified version of the NC-stat that was cleared for marketing on October 2, 1998 (K982359). The proposed NC-stat has been modified to extend the nerve testing capability to include the ulnar nerve. The modified device can be used for evaluation of both median and ulnar neuropathies.

The ulnar nerve extension required the addition of a second biosensor configured to optimize stimulation of the ulnar nerve and acquisition of the evoked CMAPs

(compound muscle action potentials) and F-waves. Several software algorithms were expanded to support the stimulation of the ulnar nerve and detection of ulnar CMAPS when the ulnar nerve biosensor is used.

5. INTENDED USE

The NeuroMetrix NC-stat is intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The NC-stat is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Like the parent NC-stat, the proposed device consists of a hand-held, battery-powered monitor, single-use disposable sensors, a docking station to download data from the non-volatile memory, and software modules that control all the functional units of the device. The proposed and parent NC-stat monitors operate using two electrically isolated 1.5V batteries.

The docking station hardware of the proposed device is also identical to the docking station of the parent device. The protocols used for communication between the monitor and docking are also identical for the proposed and parent devices.

The parent NC-stat was cleared for marketing with a single biosensor configured for optimal stimulation of, and detection of impulses from, the median nerve. The proposed NC-stat has a median nerve biosensor identical to the median biosensor of the parent device. The proposed device also has a second biosensor configured for optimal stimulation of the ulnar nerve and maximization of the takeoff from baseline of the ulnar-evoked CMAP.

The basic design and materials used for construction of the ulnar biosensor are identical to the design and materials of the median nerve sensor described in K982359. Both the proposed ulnar sensor and the median sensor are disposable and contain detection, stimulation, and reference electrodes as well as a temperature detector. The ulnar nerve biosensor is available in two models, one for the left wrist and the other for the right wrist.

7. DESIGN CONTROL CONSIDERATIONS FOR "SPECIAL 510(K) STATUS"

The modified NC-stat was developed in accordance with the NeuroMetrix Design Control Procedure. A Hazard Analysis was performed on the modified NC-stat to identify basic faults within the device that could potentially affect the patient, end user or manufacturing personnel. All identified hazards were addressed by standard procedures. Validation testing confirmed that the modified device could stimulate the ulnar nerve and collect the evoked CMAPS to produce accurate DMLs and F-wave latencies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Neurometrix, Inc.
c/o Cynthia J. M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K000565
Trade Name: NC-stat
Regulatory Class: II
Product Code: JXE
Dated: March 27, 2000
Received: March 29, 2000

Dear Dr. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000565

Device Name: NC-stat

Indications For Use:

The NeuroMetrix NC-stat is intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The NC-stat is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000565

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____